



Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1235

[Docket No. CPSC-2016-0023]

Safety Standard for Baby Changing Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards must be substantially the same as applicable voluntary standards or more stringent than the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with a product. Pursuant to the direction under section 104(b) of the CPSIA, the Commission is proposing a safety standard for baby changing products. The proposed rule would incorporate by reference ASTM F2388-16, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use* (ASTM F2388-16) into our regulations and impose more stringent requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature. In addition, the Commission proposes to amend our regulations include the proposed safety standard for baby changing products in the list of notice of requirements (NORs) issued by the Commission.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the labeling and instructional literature requirements of the proposed mandatory standard for baby changing products should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oir_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2016-0023, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted by mail/hand delivery/courier.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, insert docket number CPSC-2016-0023 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Mark Kumagai, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2234; e-mail: MKumagai@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant or toddler products. Any standard the Commission adopts under this directive must be substantially the same as the applicable voluntary standard or more stringent, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product.

A “durable infant or toddler product,” as defined in section 104(f)(1) of the CPSIA, is “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Section 104(f)(2) lists examples of “durable infant or toddler products,” such as cribs, high chairs, and strollers. Although this list of example products does not include baby changing products, baby changing products satisfy the statutory definition, as they are intended for use by children under the age of 5 years and are durable products made of

sturdy material that last for several years; they are similar to the example products listed in the CPSIA; and the Commission has identified changing tables as “durable infant or toddler products” in the product registration rule that the Commission issued under section 104(d) of the CPSIA. 16 CFR 1130.2(a)(14).

Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with representatives of manufacturers, consumer groups, consultants, retailers, and industry trade groups in reviewing and assessing the effectiveness of the existing voluntary standard for baby changing products, ASTM F2388-16, largely through ASTM International’s (ASTM; formerly the American Society for Testing and Materials) standard-development process. The standard the Commission proposes in this notice of proposed rulemaking (NPR) is based on ASTM F2388-16 with more stringent requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature.

The testing and certification requirements of section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089) apply to the standards promulgated under section 104 of the CPSIA. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third party conformity assessment bodies (*i.e.*, test laboratories) to assess whether a children’s product conforms to applicable children’s product safety rules. If adopted, the proposed rule for baby changing products would be a children’s product safety rule that requires the issuance of an NOR. For this reason, this NPR also proposes to amend 16 CFR part 1112 to include a reference to proposed 16 CFR part 1235, the section in which the standard for baby changing products would be codified.

II. The Product

A. Definition

ASTM F2388-16 applies to baby changing tables and other changing products. The standard defines “changing tables” as “elevated, freestanding structures” designed “to support and retain a child” with a body weight up to 30 pounds (13.6 kilograms) for the purpose of a diaper change. Changing tables may convert to other furniture pieces, such as dressers or play yards, and they may have storage or other pull-out or drop-down features. ASTM F2388-16 also applies to other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables. Contoured changing pads have barriers designed to keep children up to 30 pounds on the pad for diaper changes on elevated surfaces. Add-on changing units are used with pieces of furniture to provide changing surfaces and/or barriers to keep children on the products during diaper changes.

The majority of changing tables and add-on changing units are made of wood; contoured changing pads are generally made of a combination of synthetic-covered foam. Changing tables come in various designs, some of which include drawers, cabinets, or retractable stairs.

Throughout this NPR, the Commission uses the term “baby changing products” to refer to changing tables and other changing products, such as contoured changing pads and add-on changing units that are sold separately for use on furniture products other than changing tables.

B. Market Description

Commission staff identified 85 firms, including manufacturers, importers, and wholesalers, that supply baby changing products to the U.S. market. Seventy-one of these firms are domestic, consisting of 57 manufacturers, 12 importers, one wholesaler, and one retailer; 14 are foreign, consisting of 12 manufacturers, one importer, and one retailer. Of the domestic

firms, 59 are small businesses, as discussed in Section XI. Regulatory Flexibility Act, below, and 12 are large. Eighty-one of the firms market their products to consumers, while seven also market them for commercial daycare use. Fifty-six of the firms offer multiple baby changing products.

Stand-alone changing tables intended for home use range widely in price, from approximately \$35 to \$1,400. Other baby changing products also vary greatly in price. Contoured changing pads range from about \$7 to \$100; add-on changing units, such as changing trays, range from approximately \$12 to \$1,050; and other baby products, such as cribs, play yards, dressers, and bath tubs, with attachable or built-in baby changing products, range from approximately \$100 to \$4,500.

III. Incident Data

The Commission receives data regarding product-related injuries from several sources. One such source is the National Electronic Injury Surveillance System (NEISS), from which CPSC can estimate the number of injuries associated with specific consumer products that are treated in U.S. hospital emergency departments (EDs) nationwide, based on a probability sample. Other sources include reports from consumers and others through the Consumer Product Safety Risk Management System (which also includes some NEISS data) and reports from retailers and manufacturers through CPSC's Retailer Reporting System (collectively referred to as Consumer Product Safety Risk Management System data (CPSRMS)).

Commission staff reviewed the NEISS and CPSRMS databases for incidents involving baby changing products involving children younger than 3 years old because that age corresponds with the 30-pound weight limit in the definition of "changing tables." *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, National Center for Health Statistics, *Data Table of*

Infant Weight-for-Age Charts, http://www.cdc.gov/growthcharts/html_charts/wtageinf.htm (last visited Aug. 5, 2016) (indicating 30 pounds is the 50th percentile weight of boys at 31 months old and girls at 34 months old). Staff considered CPSRMS data from January 1, 2005 through December 31, 2015, and NEISS data from January 1, 2005 through December 31, 2014 (NEISS data was not yet updated for 2015 at the time of analysis).

Through CPSRMS sources, the Commission has received 182 reports of incidents related to baby changing products that occurred between 2005 and 2015. These reports include five fatalities, 30 injuries or adverse health problems, 113 incidents that did not result in injuries, and 34 incidents for which the Commission did not receive sufficient information to determine whether an injury occurred.

EDs participating in NEISS reported 1,305 injuries and no deaths related to baby changing products between 2005 and 2014. Extrapolating from this probability sample, there were approximately 31,780 injuries and no fatalities related to baby changing products treated in EDs between 2005 and 2014. In analyzing the number of injuries that occurred each year between 2005 and 2014, Commission staff found that there was a statistically significant increasing trend in injuries over this period. The NEISS data also indicates that the incidence of injuries was the same for males and females and that 75 percent of the injured children were under 1 year old.

A. Fatalities

The Commission received reports of five fatalities associated with baby changing products between 2005 and 2015. The five reported deaths all involved caregivers using baby changing products as sleep products, which is not their intended use. All of the victims in these incidents were younger than 1 year old.

Four of the incidents involved play yards with changing table attachments. In one of these cases, a strap hanging from a changing table accessory in a play yard strangled a child sleeping in the play yard beneath. In the remaining four deaths, children asphyxiated while sleeping on a baby changing product; three of the products were the changing table attachments on play yards, and one was a portable changing pad placed in a crib as a sleep positioner.

In three of the reports regarding these fatalities, the caregivers and investigators appeared to be mistaken about the intended use of the product, referring to the changing table product as a “crib” and “bassinet.”

B. Nonfatal Injuries

Of the 182 CPSRMS incidents related to baby changing products that occurred between 2005 and 2015, 30 reportedly resulted in injuries or adverse health problems. The most frequently cited injuries were cuts, lacerations, scratches, and bruises; however, there were several more serious injuries reported as well. Three reports indicated that the victim visited the hospital; in one incident involving a leg injury, the victim was treated and released, and in two incidents involving a skull fracture and leg fracture, respectively, the victims were admitted to hospitals.

For injuries estimated through NEISS, 94 percent were treated and released, while 5 percent were admitted to the hospital. The most commonly injured body parts were the head (71 percent) and face (13 percent). The most common types of injuries were injuries to internal organs (50 percent), contusions or abrasions (27 percent), and fractures (9 percent). Of those injuries affecting internal organs, 99 percent were head injuries; of those injuries resulting in contusions or abrasions, 83 percent affected the victim’s head or face.

C. Hazard Pattern Identification

CPSC staff reviewed NEISS and CPSRMS data to identify hazard patterns associated with baby changing products. Both sets of data revealed several common hazard patterns, but because CPSRMS data sources generally provide greater detail about incidents, staff was able to identify more distinct hazard patterns using that data. Five hazard patterns emerged from staff's review: (1) issues with structural integrity, (2) design hazards, (3) problems with restraint systems, (4) miscellaneous problems, and (5) undetermined hazards. Table 1 provides the frequency of each hazard pattern and category.

TABLE 1.—*Hazard Patterns for CPSRMS Incidents Involving Baby Changing Products between January 1, 2005 and December 31, 2015*

Hazard Pattern	Total Incidents
Structural Integrity	119
Design	38
Restraint System	14
Miscellaneous	8
Undetermined	3

Structural integrity issues include collapsing or unstable products, hardware issues, and assembly problems. This hazard pattern accounted for approximately 65 percent of CPSRMS incident reports (119 of 182 incidents). Fifty-five percent of the reported incidents in this hazard pattern involved collapsing baby changing products or parts (with 50 percent of those reports attributable to three particular models). The next most common type of structural integrity issue was unstable baby changing products.

Product design issues included limb entrapments, in parts such as slats, rails, and doors, chipping finishes, unstable steps, pinching, children hitting their heads on metal parts, and a strangulation hazard from a restraint strap in a play yard changing table accessory.

Approximately 21 percent of incidents reported through CPSRMS (38 of 182) fell into this hazard pattern. The majority of these incidents involved accessory components that are common to other furniture, as well as changing tables, and are not generally accessible to children when occupying a changing table as intended.

About 8 percent of incidents (14 of 182) related to restraint systems, which include loose, broken, or detached straps, cracked or faulty buckles, pinching, choking on small parts, and the absence of a restraint system.

Approximately 4 percent of CPSRMS incidents (8 of 182) involved miscellaneous issues, including chemical odors and the use of changing tables for unintended purposes, such as sleeping. All of the deaths associated with baby changing products involved children sleeping on the products.

Two percent of the incident reports (3 of 182) did not provide sufficient information for Commission staff to identify a hazard pattern.

The most frequently reported event associated with an injury in both NEISS and CPSRMS data involved children falling off, or through, baby changing products. Within NEISS data, 94 percent of injuries involved falls, while 64 percent of non-fatal CPSRMS incidents involved children falling from baby changing products. These incidents were prevalent in the structural integrity and restraint system hazard patterns. Eight of the CPSRMS fall incidents were the result of the baby changing product or supporting structure collapsing. Ten of the 14 restraint system incidents resulted in actual or potential falls, and one resulted in injury.

Some of the fall incidents resulted in injuries of varying severity. Within the NEISS incidents, several of the fall injuries resulted in a serious head injury, such as a concussion or fractured skull. Ten CPSRMS incidents involving falls also resulted in injuries. One of these 10

incidents resulted in a fractured skull, one a fractured leg, seven involved minor injuries, such as bruises, scratches, and lacerations that did not require medical attention and one did not indicate the severity of injury. Additionally, in several cases, caregivers reported catching a falling child, potentially preventing injuries.

D. Product Recalls

Since January 1, 2005, two firms have recalled baby changing products. In 2006, one firm recalled approximately 130 baby changing products, due to a fall hazard. The products included cloth sections secured by zippers to support occupants. The firm found that if the zipper was misaligned, the cloth section supporting an occupant could detach. In 2007, a second firm recalled approximately 425,000 baby changing products. The product was an infant play yard with a raised changing table accessory that had a restraint strap that formed a loop beneath the changing table, posing a strangulation hazard to a child in the play yard. This recalled product was associated with one child's death.

IV. International Standards for Changing Tables

CPSC is aware of two international standards that apply to baby changing products:

- ASTM F2388-16, and
- British/European Standard BS EN 12221: 2008, *Child use and care articles—Changing units for domestic use, Part 1: Safety requirements, Part 2: Test methods* (European standard).

CPSC staff reviewed the provisions in these standards and believes that ASTM F2388-16 best addresses the hazard patterns indicated in the incident data, and in most areas, ASTM F2388-16 includes more stringent requirements than the European standard. For example, although both standards require barrier durability testing, ASTM F2388-16 requires pre-

conditioning or aging of contoured changing pads before testing. In contrast, the European standard does not require precondition or aging, which makes ASTM F2388-16 the more stringent standard.

There are some areas in which the European standard includes more stringent requirements than ASTM F2388-16. For example, the European standard limits the dimensions of cords and loops, while ASTM F2388-16 does not. However, the incident data does not indicate that cords or loops present a safety hazard, apart from the one strangulation death involving a loop in a play yard, but the play yard standard has since been updated to address that hazard. In reviewing this and other provisions in which the European standard is more stringent than ASTM F2388-16, Commission staff found that the incident data does not indicate that the more stringent requirement is necessary to reduce the risk of injury, and further determined that the requirements in ASTM F2388-16 are sufficient.

Some requirements in the two standards differ in ways that make it difficult to compare their relative stringency. Nevertheless, for these requirements, Commission staff believes that ASTM F2388-16 arguably is more stringent, the incident data does not demonstrate that the European standard is necessary, or the additional requirements proposed in this NPR are the most effective method of addressing the risk. For example, the stability tests in ASTM F2388-16 and the European standard differ in ways that make them difficult to compare, but the incident data indicates that tip-over incidents are not an issue, which suggests that ASTM F2388-16, to which many manufacturers conform, is adequate. Likewise, the load tests in ASTM F2388-16 and the European standard differ, but staff believes that the ASTM test reflects actual load conditions better. Moreover, this NPR proposes additional, more stringent requirements for this test that are not in either standard.

Based on these comparisons, CPSC believes that ASTM F2388-16, in general, is more stringent than the European standard and is better tailored to address the hazard patterns evident in the incident data.

V. ASTM F2388-16

A. History of ASTM F2388-16

ASTM first approved and published a standard for baby changing products in July 2004, as ASTM F2388-04, *Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use*. ASTM has revised the voluntary standard several times since then, adding and modifying requirements. Some of the more substantial revisions, to date, include:

- expanding the scope of the standard to include changing table products, such as contoured changing pads and add-on changing units;
- requiring preconditioning before conducting barrier testing on contoured changing pads;
- marking packaging with the maximum occupant weight; and
- requiring toy accessories to comply with applicable safety requirements.

ASTM approved the current version of the standard, ASTM F2388-16, on July 1, 2016.

B. Description of ASTM F2388-16

CPSC staff, together with stakeholders on the ASTM subcommittee task group for baby changing products, developed modified and new requirements for ASTM F2388-16 to address the hazards associated with these products. ASTM F2388-16 includes the following key provisions: scope, terminology, calibration and standardization, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. The

following provides an overview of these provisions. To view the complete standard, see the instructions in Section IX. Incorporation by Reference.

1. Scope

This section states the scope and intent of the standard.

2. Terminology

This section provides definitions of terms specific to the standard.

3. Calibration and Standardization

This section provides general instructions for conducting tests.

4. General Requirements

This section includes general requirements addressing various safety issues, such as sharp edges and points, small parts, lead in paint, wood parts, openings, changing table attachments to play yards and non-full-size cribs, and toy accessories.

5. Performance Requirements and Test Methods

These sections contain performance requirements and associated test methods for baby changing products. The following summarizes key requirements in these sections.

- a. Protective Components: These requirements provide for testing protective components, such as caps and plugs.
- b. Structural Integrity: A changing table must not break or fail any other requirements after applying a specified weight for a set time period. The purpose of this requirement is to test whether changing tables can withstand the loads they will bear. Contoured changing pads and add-on changing units that are sold separately are not subject to this requirement.

- c. **Stability:** A changing table must not tip over when pushed downward by a specified force on the edge most likely to cause the product to tip over. The purpose of this requirement is to test the changing table's resistance to tipping over if there is weight on the edge of the product. Contoured changing pads and add-on changing units that are sold separately are not subject to this requirement.
- d. **Barriers:** Baby changing products must include barriers that are integral to the product. These barriers must be on all sides of flat changing surfaces and two sides of contoured surfaces. Barriers must not break or fail any other requirements or allow a test object to fall when holding a rolling test weight at an incline. Contoured changing pads must withstand this test after preconditioning or aging. The purpose of this requirement is to prevent children from rolling off of baby changing products or being injured by damaged barriers.
- e. **Retention of Contoured Changing Pads and Add-on Changing Units:** Contoured changing pads and add-on changing units must not move more than a specified distance during the barrier testing described above. The purpose of this requirement is to prevent children from falling when they move on baby changing products. Changing table accessories for non-full-size cribs and play yards are not subject to this requirement because they are subject to a similar requirement in another standard.
- f. **Entrapment in Enclosed Openings:** Any completely-bounded openings that are accessible to children in or near the base of a changing table must meet specified dimension limits for gaps and openings. The purpose of this requirement is to prevent children's heads from becoming entrapped in openings.

- g. Entrapment by Shelves: Any shelf that is not enclosed in doors and that is within a specified distance from the floor must not permit a probe, designed to simulate a child's head, to pass through. The purpose of this requirement is to prevent children from becoming entrapped in shelves on baby changing products.

6. Permanency of Labels and Warnings

This section specifies testing and criteria for determining the permanency of labels.

7. Marking and Labeling

This section contains various requirements related to warnings, package markings, and labels including content, format, and placement requirements.

8. Instructional Literature

This section requires instructions to accompany baby changing products, be easy to read and understand, and include specific content.

C. Ongoing Revisions of ASTM F2388-16

ASTM, with the participation of CPSC staff, has continued to review the effectiveness of ASTM F2388-16 in light of incidents and hazard patterns. As a result, ASTM has developed additional requirements that are currently under review. ASTM participants have voted on some of these changes and submitted comments, and the committee reviewing ASTM F2388-16 is working to resolve these comments. The requirements that the Commission proposes in this NPR that are more stringent than the requirements in ASTM F2388-16 are the same as, or similar to, the requirements ASTM is currently reviewing. ASTM has authorized the Commission to print requirements that are the same as, or similar to, those ASTM drafted and is currently reviewing.

Additionally, an ASTM group, referred to as the ASTM Ad Hoc Wording Task Group, with CPSC staff's input, has reviewed warning requirements, in general, to develop one set of

requirements that would be useful for various standards. The ASTM Ad Hoc Wording Task Group developed recommendations for product warnings, particularly focusing on form, to provide effective and uniform warning requirements that can be adapted for various products. The goal of this effort was to have one consistent set of requirements from which ASTM committees could draw and adjust, as necessary, when developing or revising individual product standards. The result of the group's work is a set of recommendations, rather than a formalized standard. The ASTM Ad Hoc Wording Task Group requested ASTM participants' input on these recommendations in early 2016, received feedback, and has since finalized its warning recommendations. However, as the group continues to review issues, it may revise and update these recommendations. The labeling and instructional literature requirements that the Commission proposes in this NPR that differ from those in ASTM F2388-16 are drawn from the ASTM Ad Hoc Wording Task Group's recommendations. ASTM authorized the Commission to publish content from these recommendations in this NPR.

Because of the ongoing review and revision of ASTM F2388-16 and the ASTM Ad Hoc Wording Task Group's recommendations, the Commission may, after reviewing comments, finalize the rule as proposed in this NPR or incorporate by reference a revised ASTM standard if that standard adopts changes consistent with the requirements that the Commission proposes in this NPR.

VI. Assessment of ASTM F2388-16

CPSC staff evaluated ASTM F2388-16 in light of the fatalities, injuries, and non-injury incidents associated with baby changing products that occurred between January 1, 2005 and December 31, 2015 to determine whether the voluntary standard addresses the risk of injury associated with baby changing products or whether a more stringent standard would further

reduce the hazards. CPSC believes that ASTM F2388-16 effectively addresses the hazards indicated in the incident data, with the exception of three areas—structural integrity, restraint system integrity, and warnings on labels and in instructional literature. CPSC proposes more stringent requirements for these areas to further reduce the risk of injury associated with baby changing products.

This section provides CPSC’s assessments of how ASTM F2388-16 addresses the hazard patterns shown in the incident data.

A. Structural Integrity

There were 119 CPSRMS incidents involving the structural integrity of baby changing products. The most common incidents in this category involved unstable changing tables and collapses, with the majority of incidents (55 of 119) involving changing table surfaces cracking or collapsing. More than half of these reports involved three particular changing table models. Falls resulting from these instability issues or collapses made up the majority of injuries reported through NEISS and 80 percent of the injuries reported through CPSRMS.

Although most of the reported collapses resulted in minor injuries, such as scrapes and bruises, falls have the potential for serious injuries, such as severe head injuries, which can have long-term effects. As mentioned, some fall injuries have resulted in serious head injuries, such as concussions and fractured skulls, or other fractured bones. Serious head injuries, such as concussions and skull fractures, can cause extensive brain damage and affect development.

The next most common problem in this category was unstable baby changing products, half of which involved cantilevered changing accessories for play yards tilting under the weight of an occupant. No injuries were reported for these incidents.

ASTM F2388-16 has two provisions intended to address the structural integrity of changing tables—a stability test and a structural integrity test. The stability test requires a product to remain upright when testers apply a load that is greater than the maximum recommended weight limit for product occupants to the edge most likely to tip over. The structural integrity test requires baby changing products to withstand a specified load for a set amount of time, without damage.

In addition, ASTM F2388-16 requires baby changing products to have warning labels with specific content about fall hazards, and requires instructions on secure use of contoured changing pads and add-on changing units. ASTM F2388-16 also includes form and placement requirements for warnings and similar content requirements for instructional literature to make the warnings and instructions visible and understandable.

The stability and structural integrity tests have been in ASTM F2388, in a similar form, since ASTM first published the standard in 2004. However, despite these requirements, the incident data still reveals a high occurrence of structural integrity issues. Likewise, fall incidents continue, despite the warnings required in ASTM F2388-16. Therefore, CPSC believes that more stringent requirements would further reduce the risk of injury from collapses and falls. Section VII. Description of Proposed Changes to ASTM Standard, discusses CPSC’s proposed requirements regarding threaded fasteners, secondary support straps, and warnings that address this hazard.

B. Design

There were 38 CPSRMS incidents involving design hazards. These issues included children becoming entrapped in gaps between vertical slats and beneath horizontal rails; children pinching their fingers in drawers or doors; and problems with finishes, such as chipped surface

coatings. There was also one fatality associated with this hazard pattern, in which a changing accessory restraint strap in a play yard strangled a child.

Several general requirements in ASTM F2388-16 address this hazard pattern, including provisions on sharp points and edges, small parts, surface coatings, wood parts, and openings. ASTM F2388-16 also includes specific performance requirements for protective components and to prevent entrapments in enclosed openings and shelves. Additionally, ASTM has since revised its play yard standard to address the changing accessory restraint strap hazard.

Most of the incidents in this category involved accessory components that are common in many other types of furniture and are not accessible to children when they are in the changing table as intended. All of the pinching incidents involved children who were not on the baby changing product and involved the same hazard that is present on numerous other furniture items. Commission staff also found that the gaps in changing tables that have entrapped children's limbs are similar in size and shape to spaces between crib slats. When the Commission reviewed the same entrapment hazard for cribs, it found that reducing opening sizes may not prevent entrapments, but instead, may result in younger children being entrapped or pinched, making it difficult to develop a requirement that would prevent all entrapments.

Consequently, the Commission believes that ASTM F2388-16 adequately addresses this hazard pattern and more stringent requirements would not further reduce the risk of injury.

C. Restraint Systems

There were 14 CPSRMS incidents involving restraint systems, including broken straps, detached straps, loose or broken buckles, and concerns that products did not have restraint systems. Ten of these 14 incidents resulted in actual or potential falls, and one resulted in an injury. One of these reports, and several other fall incident reports, indicated that the caregiver

was near the child at the time of the fall, indicating that incidents can occur even when a caregiver is nearby.

ASTM F2388-16 does not include any requirements regarding restraint systems. It does not require restraint systems in baby changing products, but also does not prohibit them; nor does the standard include any performance requirements for restraint systems that are included with products. There are several factors that support not requiring restraint systems. First, barrier requirements in ASTM F2388-16 address the hazard of children rolling off of baby changing products, serving the same safety purpose as a restraint system. Second, it is difficult to design a restraint system that adequately restrains a child and also allows enough mobility for a caregiver to change the child's diaper. The most effective restraint systems are 3-point and 5-point restraints, which would limit a caregiver's ability to change a child's diaper. And third, restraints may give caregivers a sense of safety that diminishes their attentiveness.

CPSC believes that ASTM F2388-16 requirements, particularly regarding barriers, adequately address the risks that restraint systems are designed to mitigate. Accordingly, it is not necessary to require restraint systems on baby changing products. Therefore, the Commission is not proposing a more stringent requirement to mandate the presence of restraint systems on baby changing products. However, the incident data suggests that when a restraint system is present, caregivers expect it to be effective. If caregivers expect restraints to be effective, they are likely to rely on them, necessitating that the restraints function effectively when included on a product.

Because there are numerous incidents involving restraint systems breaking during normal use, the Commission considers the existing absence of restraint system requirements to be inadequate. As such, when restraints are provided, the Commission believes that more stringent requirements regarding restraint system integrity would further reduce the risk of injury. Section

VII. Description of Proposed Changes to ASTM Standard, discusses CPSC’s proposed requirements regarding restraint systems.

D. Miscellaneous

There were eight CPSRMS incidents involving miscellaneous issues with baby changing products. These reports included complaints of chemical odors and caregivers using baby changing products as sleep products. Each of the five reported deaths related to baby changing products involved children sleeping on the products. In three of these deaths, caregivers placed the child in the changing accessory of a play yard to sleep. In all three cases, the investigatory reports suggest that consumers may view baby changing products as suitable for sleep because parents and law enforcement personnel, in reporting these incidents, mistakenly referred to the play yard changing accessories as “cribs” or “bassinets.”

ASTM F2388-16 addresses the chemical content of baby changing products, requiring compliance with 16 CFR part 1303, which bans paint containing lead. Given this requirement, the low incidence of issues, and no injuries involving odors or chemicals, the Commission believes that ASTM F2388-16 adequately addresses this issue.

With respect to caregivers using baby changing products as sleep products, ASTM F2388-16 does not include any requirements to address this safety issue. However, five deaths resulted from children sleeping on baby changing products, which is not their intended use. The Commission believes that more stringent requirements are necessary to reduce the risk of injury associated with this hazard. Section VII. Description of Proposed Changes to ASTM Standard, discusses CPSC’s proposed requirements regarding warnings and instructional literature that would address this hazard.

E. Undetermined

Three CPSRMS reports involving baby changing products did not provide sufficient information for CPSC to determine how the incidents occurred. Thus, the Commission cannot assess the effectiveness of ASTM F2388-16 in addressing these issues.

VII. Description of Proposed CPSC Standard for Baby Changing Products

The proposed rule would create part 1235, titled, *Safety Standard for Baby Changing Products*. As explained, the Commission believes that ASTM F2388-16 effectively addresses the safety hazards associated with baby changing products, with the exception of structural integrity, restraint system integrity, and warnings on labels and in instructional literature. For this reason, the Commission proposes to incorporate by reference ASTM F2388-16, with modified requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature. This section discusses the proposed modifications.

A. Structural Integrity

Based on the incident data, CPSC believes that a more stringent standard for structural integrity than what is in ASTM F2388-16 would further reduce the risk of injury from collapses and falls from baby changing products. To identify requirements that would address these hazards, Commission staff reviewed incident data, evaluated design features common in baby changing products involved in incidents, and tested various baby changing products. Based on this information, Commission staff, together with ASTM, developed two provisions regarding threaded fasteners and secondary support straps to improve the structural integrity of baby changing products. Additionally, CPSC staff developed requirements for warnings in labels and instructional literature to address these issues.

1. Threaded Fasteners

Commission staff noted that many of the baby changing products involved in collapse incidents required consumers to assemble the products using self-tapping threaded fasteners, such as wood or sheet metal screws. Threaded fasteners can be difficult to install properly, and installing them incorrectly or attempting to install them multiple times can make the assembled product unstable. Multiple attempts to install threaded fasteners can strip the fastener; an over-tightened threaded fastener may crack the part it is attached to; and an under-tightened threaded fastener can create an insecure connection between parts. These issues are particularly likely with durable products, such as baby changing products, which a consumer may disassemble and reassemble for use with multiple children. Several ASTM standards for durable children's products have recognized the potential for consumers to install threaded fasteners improperly, resulting in unstable products, and certain standards prohibit them in key structural elements that consumers assemble.

For these reasons, the Commission proposes additional requirements that would provide for secure connections between fasteners and key structural elements of changing tables and products. Specifically, the Commission proposes to:

- prohibit the use of threaded fasteners on key structural elements assembled by consumers;
- require a means of preventing manufacturer-installed metal threaded fasteners used in key structural elements from loosening (such as with lock washers); and
- require a means of preventing manufacturer-installed metal inserts in key structural elements from loosening (such as by gluing).

The Commission proposes these limits for key structural elements, such as primary changing surface supports and side, end, base, and leg assemblies to address the stability of components that support the weight of occupants. CPSC believes that these more stringent standards would further reduce the risk of injury associated with baby changing products collapsing.

2. Secondary Support Straps

Commission staff examined many of the baby changing products involved in reported incidents through photographs, by collecting some of the products, and by purchasing changing tables from consumers to examine their post-use condition. Through these examinations, staff observed that several consumers had not installed secondary support straps at all, or had installed them improperly. A secondary support strap is a metal band that runs under the center of the changing surface to provide additional support. Secondary support straps are generally one of the last components that consumers install when assembling baby changing products. If a consumer does not install the strap, or installs the strap incorrectly, the product does not have the added support this feature provides to enhance the product's structural integrity.

To accurately test the structural integrity of baby changing products, the Commission believes that structural integrity testing should reflect the least structurally sound condition the product may be in when consumers use it. Given that consumers often do not install secondary support straps or install them incorrectly, products should be tested without consumer-installed secondary support straps attached. Therefore, the Commission proposes to adopt the structural integrity testing required in ASTM F2388-16, but modify the test to specify that consumer-installed secondary support straps not be installed for the test. CPSC believes that this more stringent standard would further reduce the risk of injury associated with baby changing product collapses.

B. Restraint Systems

ASTM F2388-16 does not require or prohibit restraint systems on baby changing products and does not contain any performance requirements for restraint systems that are included with these products. As discussed, although the Commission does not believe it is necessary to require restraint systems for baby changing products, the Commission does believe that a performance standard that requires restraint systems to be effective and durable when they are included with a baby changing product would further reduce the risk of injury from falls.

To develop requirements for restraint systems that would address the hazard pattern evident in the incident data, CPSC staff conducted lab testing of products and worked with an ASTM task group to review the incident data and ASTM standards addressing restraint systems in other durable children's products. As a result of this effort, the group developed a performance test for restraint systems that identifies baby changing products that were involved in restraint system failures. This test requires any restraint provided with a baby changing product to be secured on a CAMI dummy and pulled in four directions anticipated during normal use with a 30 pound force. To pass this performance standard, straps and buckles must not break or separate from baby changing products more than 1 inch from their initial adjustment positions. CPSC believes that this more stringent standard would further reduce the risk of injury associated with restraint systems, by ensuring that those included with baby changing products function effectively.

C. Warnings in Labels and Instructional Literature

As discussed, the most commonly-reported incidents involving baby changing products were falls, and the most common cause of fatalities was children sleeping on baby changing products. ASTM F2388-16 requires warnings about falls on labels and in instructional literature,

but the standard does not require any warnings about the suffocation hazard when children sleep on baby changing products. Considering the frequency and severity of reported incidents and deaths, CPSC believes that more stringent requirements would further reduce these risks of injury and death.

To develop appropriate warning requirements, Commission staff examined incident data and research on effective warnings, and worked with the ASTM Ad Hoc Wording Task Group. To further reduce the risk of injury associated with falls and children sleeping on baby changing products, the Commission proposes additional content and form provisions for on-product warning labels and parallel requirements for instructional literature. Tab E of CPSC staff's briefing package for this proposed rule includes additional details about these proposed requirements and the rationale for adding them. The briefing package is available at:

<http://www.cpsc.gov/Newsroom/FOIA/Commission-Briefing-Packages/>.

1. Content

Section 9 of ASTM F2388-16 requires baby changing products to be labeled with a warning that states: "FALL HAZARD—To prevent death or serious injury, always keep child within arm's reach." Additionally, removable pads that are intended to be attached to a support surface must warn users: "Always secure this pad to the support surface by [insert instructions on securing the changing pad]. See instructions." And for contoured changing pads and add-on changing units sold separately, warnings must specify products they attach to or specify that the support surface should be "level, stable, and structurally sound," along with the minimum support surface dimensions. Section 10 of ASTM F2388-16 requires the same warnings to appear in instructional literature for baby changing products.

ASTM F2388-16 does not include warning requirements regarding children sleeping on baby changing products.

To develop proposed warning language, Commission staff reviewed information developed through research on the content of warnings, assessed other standards, and reviewed the ASTM Ad Hoc Wording Task Group recommendations. Literature and guidelines about warnings consistently recommend that warnings include:

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions about appropriate hazard-avoidance behaviors.

Studies indicate that when a person receives information about a hazard, its consequences, and mitigating actions, that information motivates appropriate behavior.

The Commission believes that the warning statements in ASTM F2388-16 lack important details regarding fall and suffocation hazards, their consequences, and appropriate avoidance behaviors. Moreover, the Commission believes that the warning statements in the standard provide only a vague description of the types of injuries that may occur from falls and the statements do not refer to suffocation at all. The Commission believes that strengthening the requirements in ASTM F2388-16 would further reduce the risk of injury associated with falls and suffocation. Additionally, the Commission believes that these proposed changes would improve readability and consistency across standards. CPSC developed the following proposed language to describe the specific hazards, consequent injuries and dangers, and precise actions that can help reduce the likelihood of falls and suffocation. CPSC proposes to require the following warning label to appear on baby changing products:

Fall hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.

Manufacturers will select one of the terms in brackets, or a similar term, that most-appropriately describes the particular product. Similarly, CPSC proposes to require the following warning label to appear on contoured changing pads that attach to a support surface and changing products that attach to play yards:

Fall hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.
- **ALWAYS** secure this pad to the support surface by [manufacturer's instructions for securing the changing product].

Suffocation hazard. Babies have suffocated while sleeping on changing pads. Changing pad is not designed for safe sleeping.

- **NEVER** allow baby to sleep on changing pad.

Manufacturers will select one of the terms in brackets, or a similar term, that most-appropriately describes the particular product. The Commission proposes to require the same modifications to the content of the warnings in instructional literature.

Additionally, the Commission proposes minor changes to the language in section 9 of ASTM F2388-16, as detailed in the proposed regulatory text, to make the warnings clearer, and thereby, more effective and consistent with similar standards.

2. Form

Research indicates that the form of a warning can affect the extent to which consumers notice and read the warning and can communicate the seriousness of a hazard, which can affect compliance with the warning. ASTM F2388-16 does not include any form requirements for on-product warnings, apart from text size, and does not include any form requirements for warnings in instructional literature.

As discussed, Commission staff worked closely with the ASTM Ad Hoc Wording Task Group to develop recommendations for product warnings, particularly focused on form, to provide effective and uniform warning requirements. The requirements for warnings on labeling and in instructional literature that the Commission is proposing in this NPR are drawn from the ASTM Ad Hoc Wording Task Group's recommendations.

The ASTM Ad Hoc Wording Task Group's recommendations are largely consistent with ANSI Z535.4, *Product Safety Signs and Labels* (ANSI Z535.4; available at: <http://www.ansi.org/>), which provides guidance on warning label designs, specifically addressing the design, application, use, and placement of on-product warning labels. ANSI Z535.4 is the primary U.S. voluntary consensus standard for product safety signs and labels and CPSC's Division of Human Factors staff uses the standard regularly. ANSI Z535.4 includes requirements about signal words; sign and label format, arrangement, and placement; word messages; colors; borders; letter styles and sizes; and the durability of labels.

CPSC considered research on effective forms for warnings, including the requirements in ANSI Z535.4, in developing the proposed form requirements. Commission staff and the ASTM Ad Hoc Wording Task Group modified these requirements to account for the unique nature of durable nursery products, the wide range of such products, industry concerns, and insights from

CPSC's past rulemakings on durable nursery products. The resulting recommendations and the requirements the Commission proposes in this NPR are designed to increase consumer attention to warnings, improve comprehension, and increase behaviors that would minimize hazards.

These proposed requirements include:

- warnings must conform to the 2011 edition of ANSI Z535.4, which is incorporated by reference into the regulations with certain exceptions;
- warnings must be easy to read and understand, and be in English;
- warnings must be permanent;
- additional markings or labels must not contradict the required warning information or be confusing or misleading; and
- the specific typefaces, size, alignment, layout, and text formats to use to facilitate readability.

The Commission believes that these requirements would further reduce the risk of injury associated with falls and suffocation, by making the warnings regarding these risks more effective. The Commission proposes the same design requirements for on-product warnings and warnings in instructional literature, except that instructional literature need not meet the color requirements in ANSI Z535.4.

Additionally, CPSC proposes to include a note in the regulatory text, referencing ANSI Z535.6, *Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials* (ANSI Z535.6; available at: <http://www.ansi.org/>), for optional additional guidance about the design of product safety messages in instructional literature. CPSC does not propose to require compliance with ANSI Z535.6, but the standard may offer regulated entities additional useful information for developing effective warnings in instructional literature. Although the

Commission believes compliance with this standard is advisable, product instructions vary greatly, depending on the product, purpose, content, length, and other factors. Thus, the Commission believes it is appropriate to reference ANSI Z535.6, but not mandate compliance with it.

3. Placement

ASTM F2388-16 requires warning labels to be “conspicuous,” that is, visible to a caretaker standing in a place normally associated with changing a diaper. The Commission believes that this requirement is adequate because it provides caregivers the opportunity to see a warning during routine use of the product and just before they would leave a child unattended, sleeping, or out of their reach on the baby changing product. This requirement is also consistent with ANSI Z535.4.

D. Miscellaneous Additional Requirements

The Commission also proposes several additional minor changes that would further reduce the risk of injury associated with baby changing products and provide greater clarity or detail regarding requirements in ASTM F2388-16. These include:

- adding definitions for “key structural elements” and “non-rigid add-on changing unit accessory”;
- adding a provision to prohibit components attached by screws from separating more than 0.04 in. (1 mm) after structural integrity testing; and
- requiring a marking including both the address and telephone number of the manufacturer, distributor, or seller, rather than one or the other.

The proposed definitions would add clarity to the standard and are relevant to the additional requirements. “Key structural elements” are central to the proposed requirements

regarding threaded fasteners, and specific requirements for “non-rigid add-on changing unit accessories” are in the proposed labeling provisions. The separation limit would further reduce the risk of injury associated with structural integrity issues demonstrated in the incident data. Providing the address, as well as the telephone number for firms that supply baby changing products would provide the Commission and consumers with more complete contact information, in case it is necessary to contact a supplier. This would expedite any safety measures necessary and thereby, reduce the risk of safety hazards.

VIII. Amend 16 CFR Part 1112 to Include NOR for Baby Changing Products Standard

Section 14 of the CPSA establishes requirements for product testing and certification. Manufacturers of products that are subject to a consumer product safety rule under the CPSA or another rule the Commission enforces must certify, based on product testing, that their product complies with all such rules. 15 U.S.C. 2063(a)(1). Additionally, manufacturers of children’s products that are subject to a children’s product safety rule must have these products tested by a third party conformity assessment body that CPSC has accredited, and manufacturers must certify that their products comply with all applicable children’s product safety rules. *Id.* at 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children’s product safety rule. *Id.* at 2063(a)(3). Because the proposed rule is a children’s product safety rule, if the Commission issues 16 CFR part 1235, *Safety Standard for Baby Changing Products*, as a final rule, the CPSC must also issue an NOR.

The Commission published a final rule, codified at 16 CFR part 1112, titled, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, which established requirements for accreditation of third party conformity assessment bodies to test for conformity

with children's product safety rules in accordance with the CPSA. 78 FR 15836 (Mar. 12, 2013). Part 1112 also codifies all of the NORs that the Commission previously issued.

NORs for new children's product safety rules, such as the baby changing products standard, require the Commission to amend part 1112. To accomplish this, as part of this NPR, the Commission proposes to amend part 1112 to add baby changing products to the list of children's product safety rules for which CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test for compliance with the proposed standard for baby changing products would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to have 16 CFR part 1235, *Safety Standard for Baby Changing Products*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

IX. Incorporation by Reference

Section 1235.1 of the proposed rule incorporates by reference ASTM F2388-16 and ANSI Z535.4. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, in the preamble of the NPR, an agency must summarize the incorporated material and discuss the ways in which the material is reasonably available to interested parties or how the agency worked to make the materials reasonably available. 1 CFR 51.5(a). In accordance with the OFR's requirements, Section V. ASTM F2388-16 of this preamble summarizes the provisions of ASTM F2388-16 and Section VII. Description of Proposed Changes to ASTM Standard summarizes the provisions of ANSI Z535.4 that the Commission proposes to incorporate by reference.

ASTM F2388-16 is copyrighted material. By permission of ASTM, interested parties may view the standard as a read-only document during the comment period of this NPR at: <http://www.astm.org/cpsc.htm>. Interested parties may also purchase a copy of ASTM F2388-16 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>.

ANSI Z535.4 is also copyrighted material. Interested parties may purchase a copy of ANSI Z535.4 from the American National Standards Institute (ANSI), 1899 L Street, NW, 11th Floor, Washington, DC 20036, or through the ANSI website at: <https://www.ansi.org>.

Interested parties may also inspect copies of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923.

X. Effective Date

The Administrative Procedure Act (5 U.S.C. 551-559) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for baby changing products to come into compliance with the standard, the Commission proposes that the standard become effective 6 months after publication of the final rule in the *Federal Register*. Without evidence to the contrary, CPSC generally considers 6 months to be sufficient time for suppliers to come into compliance with a new standard, and 6 months is typical for other CPSIA section 104 rules. Six months is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in its certification program to transition to a new standard after publication.

The Commission also proposes that the amendment to part 1112 become effective 6 months after publication of the final rule.

The Commission requests comments on the proposed effective date.

XI. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires the Commission to prepare an initial regulatory flexibility analysis (IRFA) and make it available to the public for comment when the NPR is published. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Specifically, the IRFA must discuss:

- the reasons the agency is considering the action;
- the objectives of and legal basis for the proposed rule;
- the small entities that would be subject to the proposed rule and an estimate of the number of small entities that would be impacted;
- the reporting, recordkeeping, and other requirements of the proposed rule, including the classes of small entities subject to it and the skills necessary to prepare the reports or records; and
- the relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

5 U.S.C. 603.

This section summarizes the IRFA for this proposed rule. The complete IRFA is available in Tab F of staff’s briefing package for this proposed rule, available at:

<http://www.cpsc.gov/Newsroom/FOIA/Commission-Briefing-Packages/>. To summarize, the

Commission cannot rule out a significant economic impact for 40 of the 59 (68 percent) small entities that supply baby changing products in the U.S. market.

B. Market Description

CPSC identified 85 firms that supply baby changing products to the U.S. market. Seventy-one of these firms are domestic (57 manufacturers, 12 importers, one wholesaler, and one retailer), and 14 are foreign (12 manufacturers, one importer, and one retailer). Eighty-one of these firms market their products to consumers, while seven also market their products for commercial daycare use. Fifty-six offer multiple types of baby changing products.

C. Reason for Agency Action, Objectives, and Legal Basis for Proposed Rule

Section 104 of the CPSIA requires the CPSC to promulgate mandatory standards for durable infant or toddler products that are substantially the same as a voluntary standard or more stringent than the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. As discussed in Section I. Background and Statutory Authority, baby changing products are durable infant or toddler products.

D. Description of the Proposed Rule

CPSC proposes to adopt ASTM F2388-16 with modifications to the structural integrity requirements, restraint system requirements, and provisions on warnings on labels and instructional literature. Section V. ASTM F2388-16 of this preamble discusses key provisions of ASTM F2388-16 and Section VII. Description of Proposed Changes to ASTM Standard discusses the proposed requirements that are more stringent than ASTM F2388-16. To help evaluate the economic impact of the proposed rule, Commission staff contacted nine industry members who would be impacted by the rule, and three responded.

E. Other Relevant Federal Rules

CPSC has not identified any federal or state rules that would duplicate, overlap or conflict with the proposed rule.

F. Impact of the Proposed Rule on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a baby changing product manufacturer is a small business if it has 500 or fewer employees; importers and wholesalers are small businesses if they have 100 or fewer employees. CPSC analyzed domestic firms because SBA guidelines and definitions apply to U.S. entities. CPSC identified 85 firms that currently market baby changing products in the United States; 71 are domestic firms. Fifty-nine of these firms (49 manufacturers, 9 importers, and 1 wholesaler) are small businesses, based on the SBA guidelines and available information about the firms.

To determine the extent to which the proposed rule would impact small businesses, the Commission identified firms that comply with ASTM F2388-16 by considering the following factors: JPMA certification, the firm's claims of compliance, active participation in ASTM standards development, and CPSC compliance testing. Table 2 lists the number of firms by location, size, type, and compliance:

TABLE 2.—*Firms that Market Baby Changing Products in the U.S.*

Category	Number of Firms
Domestic	71
Small	59
Manufacturers	49
Compliant with ASTM F2388	22
Not Compliant with ASTM F2388	27
Importers and Wholesalers	10
Compliant with ASTM F2388	4
Not Compliant with ASTM F2388	6
Large	12
Foreign	14
Total	85

Looking first at the proposed requirements that would prohibit the use of consumer-installed threaded fasteners in key structural elements, the Commission believes that the overall economic impact of this requirement would be small. CPSC testing indicates that most baby changing products on the market already follow this restriction and non-compliant firms could make inexpensive changes to meet this requirement.

With respect to structural integrity testing without consumer-installed secondary support straps, it is possible that some firms would incur costs to comply with this requirement. CPSC testing indicates that some products do not pass structural integrity testing without their consumer-installed secondary support straps; however, these products are not currently on the market. The cost of complying would vary, depending on the modifications that a firm adopts.

Next, the Commission proposes to adopt a structural integrity test for restraints when they are included with a product. The Commission found that approximately 21 percent of baby changing products on the U.S. market include restraints. Through limited testing, staff found that some of these products do not meet the proposed requirement. To comply with the proposed requirement, firms have several low-cost options to reinforce restraints.

Finally, the Commission is proposing additional requirements for warnings on labels and in instructional literature. All firms would have to modify the wording and format of their warnings to meet these requirements; however, the costs of such changes are generally small, particularly compared to overall firm revenues.

1. Small Manufacturers with Compliant Baby Changing Products

Of the 49 small manufacturers, 22 produce baby changing products that comply with ASTM F2388-16, making the economic impact of adopting ASTM F2388-16 small.

Additionally, the proposed requirements for threaded fasteners, restraints, and warnings likely would also create only small costs for these manufacturers. Compliant manufacturers are unlikely to use consumer-installed threaded fasteners in key structural components because other children's product standards prohibit them. About 10 of these firms produce at least one baby changing product with restraints, but if their products are not compliant, then the firm can remove the restraints or make other low-cost adjustments. Similarly, the cost to comply with the proposed requirements for warnings is also likely to be low because the additional requirements would merely modify the text and format of the ASTM F2388-16 warnings.

In contrast, the proposed additional requirement regarding user-installed secondary support straps may result in significant costs. Five of the compliant manufacturers may use consumer-installed secondary support straps. If these products do not pass the structural integrity test without these supports, the cost of modifying the products could range from minimal to great, depending on the product type and the changes employed. Therefore, staff cannot rule out a significant economic impact for the five manufacturers of compliant products that may employ user-installed secondary support straps.

2. Small Manufacturers with Non-Compliant Baby Changing Products

Twenty-seven of the 49 small manufacturers produce baby changing products that do not comply with ASTM F2388-16. These firms may incur costs to conform to ASTM F2388-16 and the additional proposed requirements. The Commission does not have sufficient information to determine the extent and cost of these changes. Therefore, the Commission cannot rule out a significant economic impact on these firms.

3. Third Party Testing Costs for Small Manufacturers

Under section 14 of the CPSA, if CPSC adopts the proposed requirements, all manufacturers would be subject to the third party testing and certification requirements under 16 CFR part 1107. Third party testing would include any physical and mechanical test requirements, and the cost of obtaining testing would be in addition to the costs of meeting the baby changing products standard.

Almost half of small baby changing product manufacturers (22 out of 49) already test their products for compliance with ASTM F2388, although not necessarily through a third party laboratory. For these manufacturers, the cost of the proposed rule, with respect to third party testing, would be limited to the difference between the cost of their current testing regimes and the cost of third party tests, which is likely to be low.

Of the remaining 27 firms that do not currently test their products for compliance with ASTM F2388-16, third party testing could result in a significant economic impact for five firms. Testing costs may exceed 1 percent of gross revenue for these firms if five or fewer samples are tested (assuming high-end, U.S.-based testing costs of \$1,200 per model sample). CPSC could not obtain revenue information for all of the small, non-compliant manufacturers. Therefore, CPSC could not evaluate the economic impact for six firms.

4. Small Importers and Wholesalers with Compliant Baby Changing Products

CPSC considered the economic impact to importers and wholesalers together because both rely on outside firms to supply the products they distribute to the U.S. market. The four small importers that comply with ASTM F2388-16 would require modifications to meet the proposed additional requirements. However, as discussed, the costs of complying with the additional threaded fastener, restraints, and warning requirements are likely to be low.

The proposed requirement regarding user-installed secondary support straps, however, could be more costly and possibly require firms to retrofit or redesign their products. Two of the four importers may require modifications to pass structural integrity testing under this requirement. Both firms could eliminate changing products from their product lines without a significant adverse impact, but likely could not use an alternate supplier.

5. Small Importers and Wholesalers with Non-Compliant Baby Changing Products

There is insufficient information to rule out a significant impact for any of the five importers and one wholesaler of non-compliant baby changing products. Whether there would be a significant economic impact would depend on the extent of the changes required for these firms to come into compliance and the response of their suppliers, who may pass on the increased costs to the importers and wholesalers.

Four of the six importers and wholesalers with non-compliant products do not appear to have direct ties to their suppliers and may select alternative suppliers. Three of these firms supply numerous products. Thus, they could stop supplying baby changing products. However, one firm only supplies baby changing products, so there would be a significant economic impact if that firm left the market.

The remaining two firms are tied to their foreign suppliers, so they are not likely to choose alternative suppliers. However, these foreign suppliers may comply with the proposed requirements to continue to market their products in the United States. Alternatively, these firms may stop selling baby changing products altogether because they represent only a small portion of their product lines. Without sales revenues, CPSC could not determine whether exiting the baby changing products market would generate significant economic impacts.

6. Third Party Testing Costs for Small Importers and Wholesalers

Importers and wholesalers would be subject to costs similar to manufacturers' costs if their foreign suppliers do not obtain third party testing. Four importers already test their products to verify compliance with the ASTM standard. As such, their costs would be limited to the incremental costs of third party testing over their current testing regimes.

There may be significant costs for two or three firms that do not comply with the ASTM standard. For two firms, the cost of testing as few as two units per model could exceed 1 percent of their gross revenues. For a third firm, testing costs may exceed 1 percent of its gross revenue, depending on how many units per model the firm tests. CPSC was unable to obtain revenue data for one small, non-compliant wholesaler, so could not examine the size of the impact on that firm.

7. Summary of Impacts

The Commission identified 59 small firms that market baby changing products in the United States, of which 49 are domestic manufacturers and 10 are domestic importers or wholesalers. Of the 49 small manufacturers, 17 are unlikely to experience significant economic impacts if the Commission adopts the proposed rule. However, CPSC cannot rule out a significant economic impact for the remaining 32 manufacturers. For two of the small importers and wholesalers, it is likely that the proposed rule would not have a significant economic impact. However, it is possible that the proposed rule would have a significant economic impact on the remaining eight small importers and wholesalers. Therefore, to summarize, CPSC cannot rule out a significant economic impact for 40 of the 59 small firms (68 percent) operating in the U.S. baby changing products market.

8. Impacts of Test Laboratory Accreditation Requirements on Small Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a third party conformity assessment body that has been accredited by CPSC. These third party conformity assessment bodies test products for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR for third party conformity testing. CPSC has codified NORs in 16 CFR part 1112. CPSC proposes to amend 16 CFR part 1112 to establish an NOR for testing laboratories to test for compliance with the proposed baby changing products standard. This section assesses the impact of this proposed amendment on small laboratories.

CPSC conducted a Final Regulatory Flexibility Analysis (FRFA) when it adopted part 1112. 78 FR 15836 (Mar. 12, 2013). The FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were laboratories that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, including the NOR for baby changing products in part 1112 would not have a significant adverse impact on small laboratories. Moreover, CPSC expects that only a small number of laboratories would request accreditation to test baby changing products, based on the number of laboratories that have applied for CPSC accreditation to test other juvenile products. Most laboratories would already have accreditation to test for conformance to other juvenile product standards; accordingly, the only cost would be to add the baby changing products standard to their accreditation. Test laboratories have indicated that this cost is

extremely low when they are already accredited for other CPSIA section 104 rules. Therefore, the Commission certifies that the NOR for the baby changing products standard will not have a significant impact on a substantial number of small entities.

G. Alternatives

At least three alternatives are available to minimize the economic impact on small entities supplying baby changing products, while also complying with the direction of section 104 of the CPSIA.

First, the Commission could adopt ASTM F2388-16, with no modifications. Section 104 of the CPSIA directs the Commission to promulgate a standard that is either substantially the same as the voluntary standard or more stringent if the Commission determines that would further reduce the risk of injury associated with the product. Therefore, adopting ASTM F2388-16 with no modifications is the least stringent rule CPSC could adopt. This alternative would reduce the economic impact on all of the small businesses supplying baby changing products to the U.S. market. Although choosing this alternative would not reduce the testing costs associated with the rule, this alternative would eliminate the economic impact of the additional proposed requirements. This option would eliminate the cost of complying with the additional requirements for the 22 small domestic manufacturers and four small importers and wholesalers with baby changing products that conform to ASTM F2388-16. However, adopting ASTM F2388-16 with no modifications would not further reduce the risks associated with falls and suffocations.

Second, the Commission could adopt ASTM F2388-16 with the proposed modifications, except for the requirement regarding secondary support straps. This additional requirement is likely to have the largest economic impact, and removing it would reduce the impact on 11 small

suppliers (9 small manufactures and 2 small importers). However, without this requirement, the standard may not reduce the risk of injuries associated with falls as effectively.

Third, the Commission could set a later effective date for the final rule. A later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production or imports if they are unable to modify their products and secure third party testing within the required timeframe. Second, firms could spread costs over a longer period, thereby reducing annual costs and the present value of total costs. CPSC requests comments on the 6-month effective date.

H. Requested Information

The Commission would find comments on the following issues particularly helpful:

- the changes, costs, and time needed to conform to ASTM F2388-16;
- how affected firms would modify their products, the associated costs, and the time needed to meet each of the proposed requirements regarding:
 - threaded fasteners;
 - consumer-installed secondary support straps;
 - restraint system integrity; and
 - labels and instructional literature;
- whether a particular effective date, or time of year would reduce the costs associated with the proposed requirements;
- whether the costs of complying with the proposed ban of consumer-installed threaded fasteners on key structural elements would be “economically significant” (*i.e.*, amount to an impact greater than 1 percent of revenue or similar economic benchmarks);

- the types of baby changing products that include user-installed secondary support straps and their prevalence in the U.S. market;
- the extent to which firms would remove restraints entirely, rather than conform to the proposed requirement, and the associated costs;
- testing costs and incremental costs of third party testing (*i.e.*, how much moving from a voluntary to a mandatory third party testing regime would add to testing costs in total and on a per-test basis); and
- the number of products that must be tested to provide a “high degree of assurance” with respect to third party testing.

XII. Environmental Considerations

The Commission’s regulations outline the types of agency actions that require an environmental assessment (EA) or environmental impact statement (EIS). Rules that have “little or no potential for affecting the human environment” fall within a “categorical exclusion” under the National Environmental Policy Act (NEPA; 42 U.S.C. 4231-4370h) and the regulations implementing NEPA (40 CFR parts 1500-1508) and do not normally require an EA or EIS. As stated in 16 CFR 1021.5(c)(1), rules or safety standards that provide design or performance requirements for products fall within that categorical exclusion. Because this proposed rule would create design and performance requirements for baby changing products, the proposed rule falls within the categorical exclusion. Thus, no EA or EIS is required.

XIII. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under 44 U.S.C. 3507(a)(1)(D), an agency must publish the following information:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to OMB.

In accordance with this requirement, the Commission provides the following information:

Title: Safety Standard for Baby Changing Products

Description: The proposed rule would require each baby changing product to comply with ASTM F2388-16, with additional requirements regarding structural integrity, restraint system integrity, and warnings in labels and instructional literature. Sections 9 and 10 of ASTM F2388-16 contain requirements for labels and instructional literature. These requirements fall within the definition of a “collection of information” provided in the PRA at 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import baby changing products.

Estimated Burden: CPSC estimates the burden of this collection of information as follows:

TABLE 3.—*Estimated Annual Reporting Burden*

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1235.3	85	6	510	1	510

CPSC’s estimate is based on the following:

Section 9.1.1 of ASTM F2388-16 requires that the name and place of business (mailing address) or the telephone number of the manufacturer, distributor, or seller appear on each baby changing product and its retail package. The additional requirements proposed in this NPR would require both the specified address information and the telephone number, instead of a choice between the two. Section 9.1.2 of ASTM F2388-16 requires a code mark or other product identification on each product and retail package that indicates the date (month and year) of manufacture.

Eighty-five known entities supply baby changing products to the U.S. market and may need to modify their existing labels to comply with ASTM F2388-16. CPSC estimates that the time required to make these modifications is about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of six models of baby changing products. Therefore, the estimated burden associated with labels is 1 hour per model \times 85 entities \times 6 models per entity = 510 hours. CPSC estimates the hourly compensation for the time required to create and update labels is \$33.02 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” Mar. 2016, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost associated with the proposed labeling requirements is \$16,840 (\$33.02 per

hour × 510 hours = \$16,840). No operating, maintenance, or capital costs are associated with the collection.

Section 10.1 of ASTM F2388-16 requires instructions to be supplied with baby changing products. Baby changing products generally require use and assembly instructions. As such, products sold without use and assembly instructions would not compete successfully with those that supply this information. Under OMB's regulations, the time, effort, and financial resources necessary to comply with a collection of information incurred by parties in the "normal course of their activities" are excluded from a burden estimate when an agency demonstrates that the disclosure activities required are "usual and customary." 5 CFR 1320.3(b)(2). CPSC is unaware of baby changing products that generally require use or assembly instructions but lack such instructions. Therefore, CPSC estimates that no burden hours are associated with section 10.1 of ASTM F2388-16 because any burden associated with supplying instructions with baby changing products would be "usual and customary," and thus, excluded from "burden" estimates under OMB's regulations.

Based on this analysis, the proposed standard for baby changing products would impose a burden to industry of 510 hours at a cost of \$16,840 annually.

CPSC has submitted the information collection requirements of this rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this NPR).

Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;

- the accuracy of CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with modifying labels and instructional literature, including any alternative estimates.

XIV. Preemption

Under section 26(a) of the CPSA, no state or political subdivision of a state may establish or continue in effect a requirement dealing with the same risk of injury as a federal consumer product safety standard under the CPSA unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). States or political subdivisions of states may, however, apply to the Commission for an exemption, allowing them to establish or continue such a requirement if the state requirement provides a significantly high degree of protection from the risk of injury and does not unduly burden interstate commerce. *Id.* at 2075(c).

One of the functions of the CPSIA was to amend the CPSA, adding several provisions to CPSA, including CPSIA section 104 in 15 U.S.C. 2056a. As such, consumer product safety standards that the Commission creates under CPSIA section 104 are covered by the preemption provision in the CPSA. Consequently, the rule proposed in this NPR would be a federal consumer product safety standard, and the preemption provision in section 26 of the CPSA would apply.

XV. Request for Comments

This NPR begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for baby changing products and to amend part 1112 to add baby changing products to the list of children's product safety rules for which CPSC has issued an NOR. We invite all interested persons to submit comments on any aspect of the proposed mandatory safety standard for baby changing products and on the proposed amendment to part 1112. Specifically, the Commission requests comments on the following:

- the requirements in ASTM F2388-16, including their effectiveness in addressing the risks of injury associated with baby changing products and the costs of complying with these requirements;
- the additional requirements proposed for structural integrity, specifically regarding threaded fasteners and secondary support straps, including their effectiveness in addressing the risk of injury associated with collapses and falls and the costs of complying with these requirements;
- the additional requirement proposed for restraint systems, including its effectiveness in addressing the risk of injury associated with restraints and falls and the costs of complying with this requirement;
- the additional requirements proposed for labels and instructional literature, including their effectiveness at addressing the hazards associated with falls and suffocation and the costs of complying with these requirements;
- the costs to small businesses associated with the requirements proposed in this NPR, including the costs to comply with the proposed additional requirements for structural integrity, restraint system integrity, and warnings on labels and in instructional literature;

- alternatives to the proposed requirements that would reduce impacts on small businesses;
- the proposed effective date and whether an extended effective date would further mitigate the impact on small businesses and to what extent; and
- any additional information relevant to the issues discussed in this NPR and the proposed requirements.

During the comment period, ASTM F2388-16 and ANSI Z535.4 are available for review.

Please see Section IX. Incorporation by Reference for instructions on viewing them.

Please submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this NPR.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1235

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend § 1112.15 by adding paragraph (b)(45) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(45) 16 CFR part 1235, Safety Standard for Baby Changing Products.

* * * * *

3. Add part 1235 to read as follows:

PART 1235-SAFETY STANDARD FOR BABY CHANGING PRODUCTS

Sec.

1235.1 Incorporation by reference.

1235.2 Scope.

1235.3 Requirements for baby changing products.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016.

§ 1235.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the U.S. Consumer Product Safety Commission, Office of the Secretary, 4330 East West Highway, Room 820, Bethesda, MD 20814, telephone 301-504-7923, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(a) American National Standards Institute, Inc., 1899 L Street, NW, 11th Floor, Washington, DC 20036; telephone 202-293-8020; <https://www.ansi.org>.

(1) ANSI Z535.4-2011, Product Safety Signs and Labels, 2011 (ANSI Z535.4-2011), IBR approved for § 1235.3.

(2) [Reserved]

(b) ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; telephone 877-909-2786; <http://www.astm.org/cpsc.htm>.

(1) ASTM F2388-16, Standard Consumer Safety Specification for Baby Changing Tables for Domestic Use, 2016 (ASTM F2388-16), IBR approved for § 1235.3.

(2) [Reserved]

§ 1235.2 Scope.

This part establishes a consumer product safety standard for baby changing products, including changing tables and other changing products, such as contoured changing pads and add-on changing units sold separately for use on furniture products other than changing tables.

§ 1235.3 Requirements for baby changing products.

(a) Except as provided in paragraphs (b) through (m) of this section, each baby changing product must comply with all applicable provisions of ASTM F2388-16 (incorporated by reference, see § 1235.1)

(b) Comply with ASTM F2388-16 with the additions or exclusions listed in paragraphs (c) through (m) of this section:

(c) In addition to the definitions in section 3.1 of ASTM F2388-16, the following definitions apply to this section:

(1) 3.1.14 *key structural elements, n*—side assemblies, end assemblies, base assemblies, leg assemblies, primary changing surface supports, or other components designed to support the weight of the occupant, or a combination thereof.

(2) 3.1.15 *non-rigid add-on changing unit accessory, n*—a supported changing unit that attaches to a crib or play yard designed to convert the product into a changing table typically having a rigid frame with soft fabric or mesh sides and/or bottom surface.

(d) In addition to complying with sections 5.1 through 5.7 of ASTM F2388-16, comply with the following:

(1) 5.8 *Threaded Fasteners (Wood Screws and Sheet Metal Screws)*—

(i) 5.8.1 No changing table shall require consumer assembly of key structural elements using wood screws or sheet metal fasteners directly into wood components. This shall not apply to non-key structural elements such as drawers, secondary support straps, other storage components, or accessory items.

(ii) 5.8.2 Metal inserts, with external wood screw threads for screwing into a wood component and providing internal machine threads to accommodate a machine screw, that are used to secure key structural elements shall be glued or include other means to impede loosening or detaching.

(iii) 5.8.3 Metal threaded fasteners, such as sheet metal screws and machine screws, secured into metal components and used to attach key structural elements shall have lock washers, self-locking nuts, or other means to impede loosening or detachment during the testing required by this specification, as described in section 6.2 of ASTM F2388-16.

(2) [Reserved]

(e) Instead of complying with section 6.2 of ASTM F2388-16, comply with the following:

(1) 6.2 *Structural Integrity*—When tested in accordance with 7.2, there shall be no breakage of the unit, nor shall it fail to conform to any other requirements in this specification before and after all testing. Components attached by screws shall not have separated by more than 0.04 in. (1 mm) upon completion of testing.

NOTE 1—Contoured changing pads and add-on changing units that are sold separately are exempt from this requirement.

(2) [Reserved]

(f) In addition to complying with section 6.8 of ASTM F2388-16, comply with the following:

(1) 6.9 *Restraint System*—

NOTE 2—A restraint system may be provided to restrict upward or lateral movement of the occupant's torso. Inclusion of a restraint system is not mandatory.

(i) 6.9.1 If a restraint system is installed on the product or available as an option, it shall meet the following:

(A) 6.9.1.1 A restraint system and its closing means (for example, buckle) shall not break or separate when tested in accordance with 7.8.

(B) 6.9.1.2 The anchorages shall not separate from the unit when tested in accordance with 7.8.

(C) 6.9.1.3 Restraints shall be capable of adjustment with a positive, self-locking mechanism that is capable, when locked, of withstanding the forces of tests in 7.8 without allowing restraint movement or slippage of more than 1 in. (25.4 mm).

(ii) [Reserved]

(2) [Reserved]

(g) Instead of complying with section 7.2 of ASTM F2388-16, comply with the following:

(1) *7.2 Structural Integrity*—Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed. Place the unit on the test floor, center a 6 by 6 in. (150 by 150 mm) wood block on the changing surface and gradually apply a 100 lb (45.4 kg) weight onto the wood block within a period of 5 s. Maintain the weight for an additional period of 60 s.

(2) [Reserved]

(h) Instead of complying with section 7.4 of ASTM F2388-16, comply with the following:

(1) *7.4 Barrier Structural Integrity and Retention Tests:*

(i) *7.4.1 Test Equipment and Test Set Up*

(A) *7.4.1.3 Test Set Up*—Assemble the unit in accordance with the manufacturer's assembly instructions. If the product design employs secondary support bars or straps beneath the changing surface that are not factory preassembled in their intended use position, this test is to be conducted without the support bars/straps installed.

(B) [Reserved]

(ii) [Reserved]

(2) [Reserved]

(i) In addition to complying with section 7.7 of ASTM F2388-16, comply with the following:

(1) *7.8 Restraint System*—

(i) 7.8.1 Secure the unit in its recommended use position so that it cannot move in the direction of the force being applied.

(ii) 7.8.2 Secure a CAMI Infant Dummy, Mark II on the changing surface in accordance with the manufacturer's instructions.

(iii) 7.8.3 Adjust the restraint, using the webbing tension pull device shown in Figure 1, below, so that a force of 2 lbf (9 N) applied to the restraint will provide a 1/4 in. (6 mm) space between the restraint and the CAMI Dummy.

(iv) 7.8.4 Using the webbing tension pull device shown in Figure 1, below, perform the following tests without readjusting the restraint system.

(A) 7.8.4.1 Within 5 s, gradually apply a pull force of 30 lbf (200 N) on the restraint strap and maintain for an additional 10 s. Release the restraint strap. Repeat this test for a total of four pulls in the following directions: horizontally away from the table in the direction an occupant could roll, in a direction that is 45 degrees from the horizontal changing surface towards the head of the changing pad, in a direction that is 45 degrees from the horizontal changing surface towards the foot of the changing pad, and vertically straight up away from the changing pad.

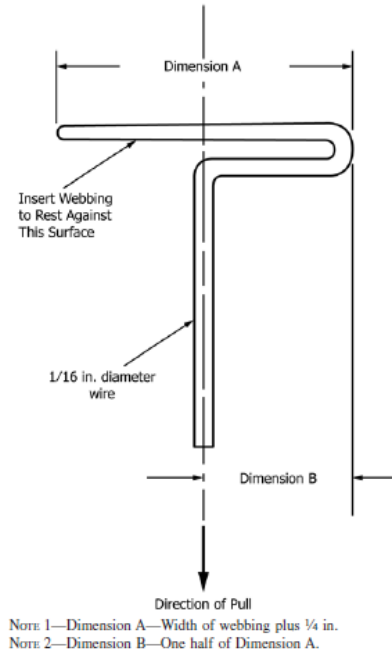


FIGURE 1.—*Webbing Tension Pull Device*

(B) [Reserved]

(2) [Reserved]

(j) Instead of complying with sections 9.1.1 and 9.1.2 of ASTM F2388-16, comply with the following:

(1) 9.1.1 The name, place of business (mailing address, including city, state, and zip code), and telephone number of the manufacturer, distributor, or seller.

(2) 9.1.2 A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

NOTE 3—Add-on changing units, non-rigid add-on changing unit accessories, or contoured changing pads sold with non-full size cribs and play yards are exempt from the labeling requirements of 9.1.1 and 9.1.2, as labeling requirements for these accessories are included in Consumer Safety Specification F406.

(k) Instead of complying with section 9.3 of ASTM F2388-16, comply with the following:

(1) 9.3 The marking and labeling on the product shall be permanent.

(2) [Reserved]

(l) In addition to complying with section 9.3, as revised in paragraph (k) of this section, comply with the following:

(1) 9.4 *Warning Design for Product*

(i) 9.4.1 The warning shall be easy to read and understand and be in the English language at a minimum.

(ii) 9.4.2 Any marking or labeling provided in addition to those required by this section shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer.

(iii) 9.4.3 The warnings shall be conspicuous and permanent.

(iv) 9.4.4 The warnings shall conform to sections 6.1-6.4, 7.2-7.6.3, and 8.1 of ANSI Z535.4-2011 (incorporated by reference, see § 1235.1), with the changes indicated in paragraph (l)(1)(iv)(A), (B), and (C) of this section

(A) 9.4.4.1 In sections 6.2.2, 7.3, 7.5, and 8.1.2, replace “should” with “shall.”

(B) 9.4.4.2 In section 7.6.3, replace “should (when feasible)” with “shall.”

(C) 9.4.4.3 Strike the word “safety” when used immediately before a color (*e.g.*, replace “safety white” with “white”).

(v) 9.4.5 The safety alert symbol and the signal word “WARNING” shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case shall be at least 0.1 in. (2.5 mm), except where otherwise specified.

NOTE 4—For improved warning readability, the warning designer should avoid the use of typefaces with large height-to-width ratios, which are commonly identified as “condensed,” “compressed,” “narrow,” or similar.

(vi) 9.4.6 *Message Panel Text Layout*

(A) 9.4.6.1 The text shall be left aligned, ragged right for all but one-line text messages, which can be left aligned or centered.

NOTE 5—Left aligned means that the text is aligned along the left margin, and, in the case of multiple columns of text, along the left side of each individual column.

(B) 9.4.6.2 The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(vii) 9.4.7 An example warning in the format described in this section is shown in Figure 2, below.

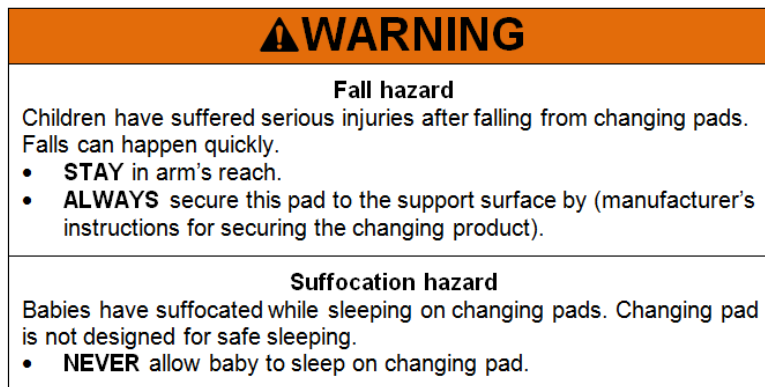


FIGURE 2.—*Example Warning*

(2) 9.5 *Warning Statements*—Each product shall have warnings statements to address the following, at a minimum:

(i) 9.5.1 The following warning statements shall be placed on all changing tables, including add-on changing units and contoured changing pads that are sold separately:

Fall Hazard. Children have suffered serious injuries after falling from changing [tables/pads/areas]. Falls can happen quickly.

- **STAY** in arm's reach.

NOTE 6—The words in brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.

(ii) 9.5.2 Removable pads that are included with changing tables, contoured pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately that are intended to be physically attached to the support surface shall have a warning on the pad or changing unit, and its retail packaging, to address the following:

- **ALWAYS** secure this [unit/pad] to the support [surface/frame] by (manufacturer's instructions for securing the changing unit). See instructions.

NOTE 7—The words in the brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product's marketing and instructions.

(iii) 9.5.3 Non-rigid add-on changing unit accessories, changing pads, and contoured changing pads, whether sold with the changing table or sold separately, shall include the following additional warning statements:

Suffocation Hazard. Babies have suffocated while sleeping [in/on] changing [tables/pads/areas]. Changing [table/pad/area] is not designed for safe sleeping.

- **NEVER** allow baby to sleep [in/on] changing [table/pad/area].

NOTE 8—The words in brackets provide wording options. The manufacturer should select the most appropriate term for the product and may substitute another term that is consistent with the product’s marketing and instructions.

(iv) 9.5.4 Contoured changing pads, non-rigid add-on changing unit accessories, and add-on changing units sold separately shall include additional warnings addressing either: (a) The specific products to attach the contoured changing pad or add-on unit to; or (b) That the surface used should be level, stable, and structurally sound with minimum surface dimensions of “X” by “Y.”

(m) Instead of complying with section 10.1.1 of ASTM F2388-16, comply with the following:

(1) 10.1.1 The instructions shall contain the warnings as specified in 9.5 and address the statements in 10.1.1.1 through 10.1.1.8. These required warning statements shall meet the requirements described in 9.4, except for the color requirements provided in ANSI Z535.4-2011, (*e.g.*, the background of the signal word panel need not be a specific color).

NOTE 9—For additional guidance on the design of warnings for instructional literature, please refer to the most-recent edition of ANSI Z535.6, Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials, American National Standards Institute, Inc., available at <http://www.ansi.org/>.

(2) [Reserved]

Dated: September 14, 2016

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

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